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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,772	12/03/2003	David D. Nolte	12258-0021	4208

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EXAMINER	
RAMILLANO, LORE JANET	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/726,772	NOLTE ET AL.	
	Examiner	Art Unit	
	LORE RAMILLANO	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14,16-18 and 45-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16-18 and 45-58* is/are rejected.

7)☒ Claim(s) *55 and 56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/3/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/24/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/24/08 has been entered.

Response to Amendment

Status of Claims

2. Applicant's reply filed on 12/24/08 is acknowledged. Claims 12-14, 17, 45, and 54-56 were amended; and added new claim 58. Claims 12-14, 16-18, and 45-58 are pending.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 12/24/08 is acknowledged. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

4. Claims 55 and 56 are objected to because of the following informalities: the status identifier of these claims should be changed to, i.e. "currently amended," since the claim language has been modified. Appropriate corrections are required.

Claim Interpretation

5. As to the pending claims below, which contain intended use terms, the Examiner will interpret these claims in light of the structural elements that are disclosed and not for their intended use as stated after the terms, i.e. "for," "configured," and "configured to." The terms, i.e. "for," "configured," and "configured to" are intended use terms. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The Examiner has applied references, which are capable of meeting these functions. A structure, which is capable of providing the intended use, is considered to meet the limitation of intended use recited in a claim to a device or an apparatus.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is rejected because the scope of the claim is indefinite. In particular, it does not appear that the "the optical source," supported by the originally filed disclosure, is positioned on the opposite side of the substrate from the adaptive optical element. In fig. 17 and 21 of applicant's disclosure, it

appears to show that the adaptive optical element and the optical source are on the same side of the substrate. For examination purposes, examiner will interpret that the adaptive optical element and the optical source are on the same side of the substrate.

Prior art rejections

8. In light of applicant's amendments, the rejections over the prior art are withdrawn. New rejections follow.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 12-14, 16-18, and 45-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. ("Klein," US 5900935, previously cited) in view of Virtanen (US 6312901, newly cited).

As to claims 12, 45, and 53, Klein discloses a device including:

a substrate (i.e. 26, fig. 1) including a first plurality of regions (i.e. higher bumps on substrate), and a second plurality of regions (i.e. lower bumps on substrate) without the binding receptor thereon, the second region separating individual regions of the first plurality of regions;

an optical source (i.e. 12, fig. 1) configured to generate a probe beam, the probe beam illuminating a beam spot on the substrate (i.e. Klein's structural features are capable of performing the functions recited after "configured to," and "illuminating," because such language are intended use terms);

an interferometer (fig. 1, includes elements from (26) to (46)) including an adaptive optical element (i.e. 36, fig. 2), the adaptive optical element positioned and configured to combine the reference beam and the signal beam, to form an output beam (i.e. Klein's structural features are capable of performing the functions recited after "configured to" because such language is an intended use term); and

a detector (i.e. 46, fig. 1) configured to detect the presence or absence of the first analyte based upon the output beam (i.e. Klein's structural features are capable of performing the functions recited after "configured to" and "indicates" because such language is an intended use term).

As to claims 13 and 56, Klein discloses that the probe beam (i.e. 24, fig. 1) is reflected by the substrate (i.e. 26, fig. 1) to form the signal beam (i.e. 32, fig. 1), the substrate having an upper side and a lower side, the lower side being opposite the upper side (i.e. see. 26, fig. 1), the optical source (i.e. 12, fig. 1) and the adaptive optical element (i.e. 36, fig. 1) being on the same side of the substrate (i.e. see fig. 1) (the claim language recited in these claims appear to recite the manner of operating the device since it recites the intended use of the probe beam).

As to claims 14 and 57, Klein discloses that the probe beam is transmitted through the substrate to form the signal beam, the substrate having an upper side and a lower side, the lower side being opposite the upper side (i.e. see. 26, fig. 1), the optical source (i.e. 12, fig. 1) and the adaptive optical element (i.e. 36, fig. 1) being on the same side of the substrate (i.e. see fig. 1) (the claim language recited in these claims appear to recite the manner of operating the device since it recites the intended use of the probe beam).

As to claim 18, Klein discloses that the interferometer operates in a quadrature condition (i.e. fig. 1, includes elements from (26) to (46); the language recited after "operates," is intended use language and it appears that Klein's interferometer is capable of performing the function recited after such term).

As to claims 50-52, Klein discloses that the probe beam is generally normal to a surface of the substrate and the first plurality of regions has a first height and the second plurality of regions has a second height, the second height being offset relative to the first height, and wherein the second height is offset relative to the first height by approximately one-eighth or one-fourth of a wavelength of the beam (i.e. see fig. 1).

As to claims 12 and 55, Klein does not specifically disclose a scanner.

Virtanen discloses an assay device comprising a solid support substrate to which a plurality of cleavable signal elements is attached in a spatially addressable pattern. In some embodiments of the assay device, the solid support may preferably be a plastic, and in these embodiments, is most preferably polycarbonate. The solid support in some embodiments is fashioned as a disk, preferably in dimensions compatible with detection by existing laser reflection-based detectors, such as an audio compact disk (CD) reader, a compact disk-read only memory (CD-ROM) reader, a digital video disk (DVD) reader, or the like. a scanner (i.e. "scanner," col. 5, line 54 to col. 6, line 8).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Klein's device by including a scanner, as disclosed by Virtanen, because it would be desirable to have an economical system to fabricate spatially addressable probe arrays in a simplified format that provides both for ready detection and the ability to assay for large numbers of test substances (i.e. analytes) in a fluid test sample in a single step, or a

minimum number of steps, or assay for a single test substance or analyte in a large number of fluid test samples (i.e. Virtanen, col. 2, lines 59-66).

Furthermore, with regard to the functional language recited after "configured to," "illuminates," and "interacts," Klein in view of Virtanen ("modified Klein") discloses structural features which are capable of performing the functions recited after such terms.

As to claims 16, 46, 47, and 49, the modified Klein does not specifically disclose a substrate having a plurality of spaced concentric tracks or radially extending spokes, wherein the first and second plurality of regions are arranged in an alternating pattern or in a repeating pattern.

In addition to the above, Virtanen discloses in FIGS. 11A through 11G various useful patterns of spatially addressable deposition of cleavable reflective signal elements on circular, planar disk substrates. FIG. 11A particularly identifies an address line, encodable on the disk substrate, from which the location of the cleavable spacers may be measured. In FIG. 11A, the cleavable spacer molecules are deposited in annular tracks. FIG. 12 is a schematic representation of detection of analyte-specific signals generated by the assay device of FIG. 11A. FIG. 11B demonstrates spiral deposition of cleavable signal elements, and particularly identifies a central void of the disk annulus particularly adapted to engage rotational drive means. FIG. 11C demonstrates deposition of cleavable signal elements in a pattern suitable for assay of multiple samples in parallel, with concurrent encoding of interpretive software on central tracks. FIG. 11D schematically represents an embodiment in which the assay device

substrate has further been microfabricated to segregate the individual assay sectors, thereby permitting rotation of the assay device during sample addition without sample mixing. FIG. 11E schematically represents an embodiment in which the assay device substrate has further been microfabricated to compel unidirectional sample flow during rotation of the assay device. FIG. 11F demonstrates deposition of cleavable signal elements in a spatial organization suitable for assaying 20 samples for 50 different analytes each. FIG. 11G demonstrates the orthogonally intersecting pattern created by superimposition of spiral patterns with spiral arms of opposite direction or chirality. (i.e. col. 9, lines 7-10; col. 37, line 34 to col. 38, line 2).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the modified Klein's substrate by including a plurality of spaced concentric tracks or radially extending spokes, wherein the first and second plurality of regions are arranged in an alternating pattern or in a repeating pattern, as disclosed by Virtanen, because it would be desirable to design the surface of the assay device to facilitate the quantitation of analyte concentration (i.e. Virtanen, col. 38, lines 3-6).

Furthermore, with regard to the functional language recited after "illuminates," the modified Klein discloses structural features which are capable of performing the functions recited after such term.

As to claims 17 and 45, the modified Klein does not specifically disclose a motor, and a controller comprising a tracking device and a radial control.

In addition to the above, Virtanen discloses assay device upon which software is encoded in an area spatially distinct from the patterned deposition of cleavable-reflective signal elements. The software may include information important for correct tracking by the incident laser, assay interpretive algorithms, standard control values, self-diagnostics, and the like. The software may include device drivers and software capable of uploading the diagnostic information to remote locations. The software may include patient education information for clinical assays, and may be adapted for chosen audiences. (i.e. col. 11, lines 24-39). Furthermore, Virtanen discloses in one aspect, the assay device is rotated and a fluid sample is applied near the center of the circular assay device substrate. The centrifugal forces associated with the rotation of the assay device disk distribute the fluid sample across the planar face of the solid substrate (i.e. col. 15, lines 34-43).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the modified Klein's device by including a motor, as disclosed by Virtanen, because it would be desirable to have a means to insure that the surface of the substrate is uniformly covered with a constant and uniformly distributed fluid sample (i.e. Virtanen, col. 15, lines 34-43). Furthermore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the modified Klein's device by including a controller comprising a tracking device and a radial control, as disclosed by Virtanen, because it would be desirable to have a combination of interpretative

software and the assay elements themselves on a single assay device (i.e. Virtanen, col. 38, lines 3-6).

Furthermore, with regard to the functional language recited after "illuminates," and "configured to," the modified Klein discloses structural features which are capable of performing the functions recited after such term.

As to claims 48 and 54, the modified Klein does not specifically disclose that the first and second regions are formed by microfluidic printing and having a substrate that has a first substantially planar surface lying substantially in a first plane and second substantially planar surface lying substantially in a second plane, the first plane being offset vertically from the second plane.

In addition to the above, Virtanen discloses in FIGS 4A-G the derivatization of the solid support substrate (i.e. col. 19, lines 8-32), and in FIGS. 13A-F a schematic example of stamps for use in printing oligonucleotide side members onto cleavable spacers previously attached to a solid substrate. The stamp as shown is made of two pieces, a stamp piece and a feeding piece. The stamp piece contains holes, which are filled by the required chemicals through a feeding piece containing channels. The channels in turn are connected to a glass capillary array. In this arrangement, one row of holes is filled with the same chemical. Different hole and channel patterns can be used as needed. (i.e. col. 9, lines 10-20). Virtanen further discloses that the techniques for microfabricating solid surfaces are well known in the art (i.e. col. 37, lines 55-63).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the modified Klein's device by forming the first

and second regions on the substrate by microfluidic printing, as disclosed by Virtanen, because techniques for microfabricating solid surfaces are well known in the art (i.e. col. 37, lines 55-63). Furthermore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Klein's substrate to have substantially planar surfaces, as disclosed by Virtanen, because it would be desirable to position the signal elements on predetermined sites on the substrate to permit quick and efficient identification of analytes bound to distinct signal elements and identification of multiple analytes in a single assay (i.e. col. 6, lines 23-26).

Furthermore, with regard to the functional language recited after "when," in claim 54, the modified Klein discloses structural features which are capable of performing the functions recited after such term.

As to claim 58, the modified Klein discloses the structural features recited in claim 58 (see corresponding paragraphs above) except for a receptor coating covering each of the plurality of first regions and not covering the second region.

Virtanen discloses in FIGS. 4A through 4G the preparation of the solid support substrate upon which cleavable reflective signal elements are deposited to create the assay device of this invention. A portion of a generally planer solid support is illustrated in FIG. 4A. As illustrated in FIG. 4B, the surface of the support is coated with a resist 22, e.g., a high melting point wax or the like. Next a pattern of indentations or holes 25 in the resist is created by stamping with stamp 23 containing protrusions 24, as illustrated in FIG. 4C. The pattern is highly regular and indentations are made in all sites at which cleavable spacer

molecules will desirably be located on the surface of the support. Any resist remaining at the bottom of the indentations, as illustrated in FIG. 4D, is removed, as shown in FIG. 4E. The exposed areas of the substrate 21, as illustrated in FIG. 4E, are activated or derivatized to provide for the attachment of bonding groups (e.g., amino groups) to the surface of the substrate and to any remaining resist 22, as represented in FIG. 4F. Finally, the remaining resist is removed to expose the original surface of the substrate to which amino groups are coupled at certain predetermined sites as illustrated in FIG. 4G. (i.e. col. 19, lines 8-32).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Klein's substrate to have a receptor coating covering each of the plurality of first regions and not covering the second region, as disclosed by Virtanen, because it would be desirable to position the signal elements on predetermined sites on the substrate to permit quick and efficient identification of analytes bound to distinct signal elements and identification of multiple analytes in a single assay (i.e. col. 6, lines 23-26).

Response to Arguments

13. Applicant's arguments with respect to claims 12-18 and 45-57 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORE RAMILLANO whose telephone number is (571)272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lore Ramillano/
Examiner, Art Unit 1797

2/1/09